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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,516	01/04/2002	Ashkan Imanzahrai	31505.0001	6624

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,516	IMANZAHRAI, ASHKAN	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2004 and 03 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,18,20 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,18,20 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to Applicant's amendment and remarks received August 4, 2004 and Sep. 3, 2004.

Claims 1-15, 17, 19, 21, 23-42 are cancelled. No new claims are added. Claims 16, 18, 20, 22 are currently pending.

The previous rejection of claim 16 under 35 USC 112, second paragraph, set forth in paragraph 1 of the office action mailed April 2, 2004 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous indication of allowability of claims 18, 20, 22 is withdrawn in view of the following new ground of rejection. The new ground of rejection is a result of discovering new prior art.

New Ground(s) of Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Armellino et al., 5,972,916 in view of Cass et al.

Armellino et al. teach a method and composition for treating migraine headaches and associated symptoms, i.e. nausea, phonophobia, photophobia, pain and functional disability, the method comprising administering an effective amount of a composition comprising acetaminophen, caffeine, aspirin and a pharmaceutically acceptable carrier such as a lubricants or disintegrants. The composition may be administered orally in tablet form or may be administered in liquid form. The dosing interval is daily every four to six hours. Please see the abstract; col. 2-col. 3; col. 6, lines 3-56; col. 7, lines 30-33.

Armellino et al. do not teach a method for treating migraines and associated symptoms by administering a composition additionally containing pseudoephedrine. Yet, the Examiner turns to Cass et al., which disclose various treatment strategies for migraine-related vestibulopathy, wherein Phenergan/pseudoephedrine (25 mg/60mg twice daily) is administered to patients suffering from space or motion discomfort, i.e nausea. Please see page 188, Table 8 and Conclusions, last two lines to page 189, lines 1-2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of Armellino by combining the pseudoephedrine-containing composition with the acetaminophen-containing composition of Armellino because one of ordinary skill in the art would reasonably expect the additive effect of the acetaminophen-containing composition and the pseudoephedrine-containing composition to be effective in treating motion or space

sickness, i.e nausea, associated with the migraine. Therefore, such a modification would have been motivated by the reasonable expectation of successfully and comprehensively treating a migraine and the symptoms associated therewith.

2. Claims 20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armellino et al., 5,972,916 in view of Barrie.

Armellino et al. teach a method and composition for treating migraine headaches and associated symptoms, i.e. nausea, phonophobia, photophobia, pain and functional disability, the method comprising administering an effective amount of a composition comprising acetaminophen, caffeine, aspirin and a pharmaceutically acceptable carrier such as a lubricants or disintegrants. The composition may be administered orally in tablet form or may be administered in liquid form. The dosing interval is daily every four to six hours. Please see the abstract; col. 2-col. 3; col. 6, lines 3-56; col. 7, lines 30-33.

Armellino et al. do not teach a method for treating migraines and associated symptoms by administering a composition additionally containing pseudoephedrine. However, the Examiner refers to Barrie, which discloses various drug treatments for migraine attacks, wherein one of the treatments involves administering a pseudoephedrine-containing composition as an analgesic for the treatment of pain. Please see page 918, Table 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of Armellino by combining the pseudoephedrine-containing composition with the acetaminophen-containing composition of Armellino because one of ordinary skill in the art would reasonably

expect the additive effect of the acetaminophen-containing composition and the pseudoephedrine-containing composition to be effective in treating pain associated with the migraine. Moreover, one of ordinary skill in the art would reasonably expect the pseudoephedrine-containing composition to treat pain that accompanies the photophobia or phonophobia in the migraine patient. Therefore, such a modification would have been motivated by the reasonable expectation of successfully and comprehensively treating a migraine and symptoms associated therewith.

3. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Armellino et al., 5,972,916 in view of Barrie, supra and Cass et al., supra.

Armellino et al. teach a method and composition for treating migraine headaches and associated symptoms, i.e. nausea, phonophobia, photophobia, pain and functional disability, the method comprising administering an effective amount of a composition comprising acetaminophen, caffeine, aspirin and a pharmaceutically acceptable carrier such as a lubricants or disintegrants. The composition may be administered orally in tablet form or may be administered in liquid form. The dosing interval is daily every four to six hours. Please see the abstract; col. 2-col. 3; col. 6, lines 3-56; col. 7, lines 30-33.

Armellino et al. do not teach a method for treating migraine pain and nausea by administering a composition additionally containing pseudoephedrine. However, the Examiner refers to (1) Barrie, which discloses various drug treatments for migraine attacks, wherein one of the treatments involves administering a pseudoephedrine-containing composition as an analgesic for the treatment of pain (please see page 918, Table 1) and (2) Cass et al., which disclose various treatment strategies for migraine-

related vestibulopathy, wherein Phenergan/pseudoephedrine (25 mg/60mg twice daily) is administered to patients suffering from space or motion discomfort, i.e nausea. (please see page 188, Table 8 and Conclusions, last two lines to page 189, lines 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of Armellino by combining the pseudoephedrine-containing composition with the acetaminophen-containing composition of Armellino because one of ordinary skill in the art would reasonably expect the additive effect of the acetaminophen-containing composition and the pseudoephedrine-containing composition to be effective in treating pain as well as nausea associated with the migraine. Therefore, such a modification would have been motivated by the reasonable expectation of successfully and comprehensively treating a migraine and symptoms such as nausea and/or pain.

In addressing Armellino's use of caffeine and aipirin in the methods and composition as well as the additional compounds disclosed in Cass et al. and Barrie, Applicant is reminded that the instant claims, recite “comprising" language which opens the claims and does not exclude other ingredients taught by the prior art but not claimed by Applicant. The transitional term “comprising" which is synonymous with “including," “containing," or “characterized by" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Moleculon Research Corp. v. CBS. Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986), In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)., Ex parte Davis, 80 USPQ 448, 450 (Bd. App.

1948)("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Please see MPEP 2111 .03.

Conclusion

Claims 16, 18, 20, 22 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Dec. 29, 2004

RAYMOND HENLEY III
PRIMARY EXAMINER
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